

Idaho Medicaid – Prior Authorization Therapeutic Criteria Hepatitis C Agents
Pharmacy & Therapeutics Committee
Approved April 24, 2015

DRUG NAME:

Ledipasvir/Sofosbuvir (Harvoni™)
Simeprevir (Olysio®)
Sofosbuvir (Sovaldi®)
Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir (Viekira PAK™)

COVERED USES:

Treatment of FDA approved indications for chronic hepatitis-C (HCV) infection.

AGE RESTRICTIONS:

FDA approved for ages 18 years or older.

PRESCRIBER RESTRICTIONS:

Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

INCLUSION CRITERIA (All criteria must be met):

- FDA approved HCV genotypes for chronic infection or hepatic carcinoma secondary to HCV awaiting liver transplantation.
- Liver Biopsy with a (Metavir stage F3-F4) or Batts-Ludwig scale 3-4 OR Fibroscan measurement >12.5 kPa OR ARFI value >1.75 meters/second OR radiographic imaging (CT/MRI) with features of portal hypertension, ascites, and hepatosplenomegaly OR APRI score >1.5 OR FIB-4 > 3.25 and serious extrahepatic manifestations of hepatitis C .
- Prescribed within the FDA approved indications/combinations/doses.
- Under the care of and/or collaboration with an experienced HCV practitioner.
- Documentation that the provider has discussed with patient the potential risks and benefit of HCV therapy and progression of HCV disease and a shared decision has been made for antiviral treatment.
- Adherence counseling performed and documented understanding by patient.
- Patient has no history of alcohol or substance abuse within the 6 months prior to treatment.
- Negative urine toxicology and blood alcohol laboratory test within 1 month of request.

EXCLUSION CRITERIA:

- Non-FDA approved combinations/dosing regimens.
- Patients with chronic HCV with minimal fibrosis (Metavir stage F0-F2).
- For agents prescribed in combination with ribavirin: pregnant women or those who may plan to become pregnant during the course of treatment.
- Documented ongoing non-adherence to prior medications, medical treatment or failure to complete HCV disease evaluation appointments and procedures or patient is unable to commit to scheduled follow-up/monitoring for the duration of treatment.

- History of intravenous drug abuse/alcohol dependency/substance abuse WITHOUT documented evidence of successful completion of 6 months of abstinence for injection drug use and/or substance abuse/alcohol dependency.
- Known hypersensitivity to any component of agent requested.
- Co-administration with drugs that are contraindicated with hepatitis C agent requested.
- Decompensated liver disease.
- Hepatitis C agents not recommended in patients with a history of relapse.
- Moderate to severe hepatic impairment (Child-Pugh B or C) for Viekira PAK™. Severe renal impairment (eGFR less than 30ml/min/1.73m²) or hemodialysis (Sovaldi® / Harvoni™).

REQUIRED MEDICAL INFORMATION:

- Diagnosis of chronic hepatitis C infection (ICD-9 070.4, 070.5, 070.7) with confirmed genotype of 1, 2, 3, or 4 or a diagnosis of hepatic carcinoma secondary to HCV awaiting liver transplantation (ICD-9 155.x).
- Documented evidence of fibrosis (Metavir score F3- F4) OR (Batts-Ludwig scale 3-4) OR Fibroscan measurement >12.5 kPa OR ARFI value >1.75 meters/second OR radiographic imaging (CT/MRI) with features of portal hypertension, ascites, and hepatosplenomegaly OR APRI score >1.5 OR FIB-4 > 3.25 or serious extrahepatic manifestations of hepatitis C.
 - Note: FibroSure®, FibroTest®, and FIBROSpect® are not recommended for routine use in the diagnosis of cirrhosis.
- Documentation of recent laboratory values, within 6 months of request, including LFT's, CBC, genotype, HCV RNA viral count and negative pregnancy test (if applicable).
- Patients with a history of intravenous drug/substance abuse/alcohol dependence will require documentation of successful completion of 6 months of abstinence for injection drug/substance abuse and/or alcohol dependency.
- A random urine toxicology and blood alcohol screening within 1 month of request.
- Previous history of HCV treatment (treatment naïve or treatment experienced).
- Documentation of interferon ineligibility (if applicable).

COVERAGE DURATION:

- FDA approved treatment regimens/durations.

TREATMENT/MONITORING CRITERIA:

- Healthcare provider must submit an HCV RNA viral count at 2 weeks of treatment for all genotypes to determine compliance and efficacy of treatment.
- Healthcare provider must submit an HCV RNA viral count at week 4 and 8 for 12-WEEK TREATMENT REGIMEN.
- Healthcare provider must submit an HCV RNA viral count at weeks 4 ,8 and 12 for 24-WEEK TREATMENT REGIMEN.
- Requests for renewal will be denied in patients who have not achieved HCV RNA below the limit of detection after 4 weeks of therapy or in patients who have not demonstrated a 1-log decrease in HCV RNA (response) after 4 weeks.
- All treatment must be discontinued if HCV RNA is >25 IU/ml at week 4 or at any other time point thereafter.
- Drug treatment approval will be denied if there is a discontinuation or dose reduction of any component of combination treatment plan.
- Patients with a history of substance/alcohol abuse will require monthly random urine toxicology and blood alcohol screening while on treatment.

- Healthcare provider must submit a sustained viral response (SVR) at week 12 and week 24 after successful completion of treatment.

OTHER:

The criteria Hepatitis C agents are based upon the most current evidence provided. Newer agents not reviewed by the Pharmacy & Therapeutics Committee will be evaluated on a case-by-case basis. Idaho Medicaid recognizes as new information becomes available these criteria may change and revised if necessary.

REFERENCES:

Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations.

From the Department of Veterans Affairs National Hepatitis C Resource Center Program and the Office of Public Health, March 2014; revised February 17, 2015. <http://www.hepatitis.va.gov/pdf/treatment-considerations-2015-02.pdf>

AASLD/IDSA 2014 Recommendations for Testing, Managing, and Treating Hepatitis C.

<http://www.hcvguidelines.org/full-report-view>

Product Information: SOVALDI™ oral tablets, sofosbuvir oral tablets. Gilead Sciences, Inc. Foster City, CA, 2013.

Product Information: HARVONI® oral tablets, ledipasvir sofosbuvir oral tablets. Gilead Sciences, Inc. (per manufacturer), Foster City, CA, 2014

Product Information: OLYSIO® oral capsules, simeprevir oral capsules. Janssen Therapeutics (per manufacturer), Titusville, NJ, 2014.

Product Information: VIEKIRA PAK™ oral tablets, ombitasvir/ paritaprevir/ritonavir oral tablets and dasabuvir oral tablets. AbbVie Inc. (per manufacturer), North Chicago, IL, 2014.